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TITLE: Development and Validation of a Theory Based Screening Process for Suicide Risk

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14. ABSTRACT
The ultimate objective of this study is to assist in increasing the capacity of military based health services to accurately identify persons at risk for suicide and to render effective referral dispositions. To do so we will characterize and evaluate the ability of a proposed suicide screening instrument and associated clinical decision-making algorithm to accurately identify at-risk individuals and provide appropriate treatment recommendations. Furthermore we will evaluate key theoretical questions related to distinguishing who is at most risk for actual suicide. In 2012, a change in the scope of work to our contract was approved. Conservative decision-making towards suicide risk at JBLM and Fort Hood eliminated the need for a research-only clinical assessment of subjects. Because the original study was actually powered to address the potential variance, eliminating this procedure reduced the power requirements of the study. Consequently, the recruitment target was reduced from 20,000 to 4,000 subjects. Currently we have received IRB approval from the University of Washington and are stewarding the completion of IRB approval via coordination with HRRPO and MRMC headquarters oversight as indicated by the DoD Instruction 3216.02 for recruitment at the SELF Center at JBLM. The IRB process has been complicated and required more time than expected.

15. SUBJECT TERMS
Suicide risk, military, Army, screening, interpersonal theory of suicide, decision-making algorithm

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INTRODUCTION

The ultimate objective of this study is to assist in increasing the capacity of military based health services to accurately identify persons at risk for suicide and to render effective referral dispositions. To do so we will characterize and evaluate the ability of a proposed suicide screening instrument and associated clinical decision-making algorithm to accurately identify at-risk individuals and provide appropriate treatment recommendations. Furthermore we will evaluate key theoretical questions related to distinguishing who is at most risk for actual suicide.

BODY

Accomplishing tasks in the time frame proposed in our original timeline has been challenging primarily due to the complexity of securing project sites. Colonel Bruce Crow of the Warrior Resiliency Program has been involved in aiding us from the beginning of our contract.

Ms. Rosemary Flannery was hired as the Project Manager in June 2011. Ms. Flannery has been involved in working with the University of Washington IRB committee, MRMC HRPO personnel, Madigan and Brooke Army Medical Center contacts and with the design and printing process for the research instruments.

1. **Secure Project Sites**
   We have pursued various avenues to receive permission to recruit subjects and collect data at both JBLM and Fort Hood. Specific site status is described below.

   JBLM
   JBLM is fully on board with supporting us in conducting our study there. We are waiting for final IRB approval to begin collecting data. We would like to highlight some of the milestones involved in this process. After numerous attempts to discern the appropriate individual(s) with whom to discuss our study, we were directed to Dr. Joseph Etherage, Programs and Research Chief at Madigan Army Medical Center, who in turn connected us with Dr. H. Quigg Davis, Chief at the Soldier Evaluation for Life Fitness Center where the PDHRA processing takes place at JBLM. Dr. Davis has been working with us on recruitment protocol to ensure that our study can be conducted at the SELF Center with minimal impact on the PDHRA process. To conduct our research project at JBLM we received a letter of support from Lieutenant Colonel Mary Reed, Chief of the Department of Operational Medicine and Deployment Health at Madigan.

   Fort Hood
   We are in active dialogue with Fort Hood personnel and making significant progress towards finalizing an agreement to perform data collection at Fort Hood. This site has been more complicated for us due to its distance from Seattle and thus the need to contract our research activities. We have an agreement in principle with Dr. Alan Peterson, Director of the STRONG STAR Consortium, who has agreed to subcontract with us to have his staff run our research study at Fort Hood. STRONG STAR has a long history of successful research activities at Fort Hood and is in an excellent position to be able to carry out our protocol. The details of the contract are being reviewed. Colonel Bruce Crow and Dr. Bret Moore have been involved in facilitating SRP connections for us at Fort Hood. We are waiting for Colonel Corey Costello to write a letter of support for our research project.

2. **Obtain approval from human subjects**
   Again, we would like to describe the major milestones involved in getting to our current position. After several months of developing an IRB protocol under the traditional process (i.e., DoD as IRB of record with deferral by our University) we were informed by Colonel Janine Babcock, Deputy Director of Army Human Research Protections Office that our study was eligible to use the new DoD Instruction 3216.02. As a non-engaged extramural research study funded by the DoD, the Instruction allows for the local IRB (University of Washington) to take responsibility for human subject protection issues with headquarters oversight from MRMC. As this would potentially streamline our IRB process for our research study, we decided to pursue this new procedure. We spoke with Adam Dubov, the Human

Subject Protection Administrator and Barbara Jones, Chief of Research Regulatory Service, both at Madigan who agreed we should move forward with this new procedure. This was a major change in process flow and took an additional several months before everyone involved agreed this to be the case.

After additional discussions with MRMC HRPO, Karen Eaton, a Human Subjects Protection Scientist at HRPO was assigned to guide us through the process of headquarters review. Prior to submitting our IRB documents to the University of Washington, Karen facilitated an initial review of protocol with MRMC. Following changes made to the documents based on MRMC's initial review we were in discussion with Deborah Dickstein, the IRB administrator for Committee G at the University of Washington for about a month as she was not aware of the new procedures and it took considerable effort to get the committee to act as primary reviewer.

As we are still in subcontract negotiations with STRONG STAR for the onsite administration for our research study at Fort Hood, and are still in need of a letter of support from Colonel Costello, Fort Hood was not included in our 7/9/2010 IRB review. Once we obtain all the necessary information, we will submit an IRB modification to include the Fort Hood site.

When our IRB is approved we will submit the documents to our contact at MRMC, Karen Eaton, for a headquarters review before we begin the Recruitment Phase.

3. **Recruitment, consent & administration of initial screener and supplemental questionnaires**
   Recruitment will begin at JBLM in October 2012 at the earliest. It has not been determined when recruitment will start at Fort Hood given that we are not as far along in the approval process for that site as we are at JBLM.

KEY RESEARCH ACCOMPLISHMENTS

To be determined after the Data Collection and Data Analysis phases are complete.

REPORTABLE OUTCOMES

To be determined after the Data Collection and Data Analysis phases are complete.

CONCLUSION

We are pleased to be in the completion phase of IRB approval. This is a long and complicated process, but it does have the beneficial effect of making sure that all of the details of the study are fully vetted and the specific data collection processes are well understood by everyone involved. Hence, we are optimistic that we will be ready to respond to the flow of incoming soldiers returning from deployment in late summer, early fall of 2012 and carrying through to 2013. We would also like to note that due to fortunate circumstances here at the University of Washington, Dr. Vannoy and Ms. Flannery have been able to devote time to this project without having to deplete funds from the budget at the rate initially anticipated. Hence there are adequate monies available to continue with the project even though the IRB approval process has been long.